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10/038,224	10/19/2001	Gabi Schewe	514413-3900	8623

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EXAMINER
FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/033,224	Applicant(s) Scheuer et al
	Examiner FOX	Group Art Unit 1635

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 2/27/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-33 is/are pending in the application.

Of the above claim(s) 18-26 and 28-33 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-17 and 27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☑ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☑ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that a search for Group I would uncover relevant items for Groups II and III. This is not found persuasive because Groups II and III require isolated products and processes not required by Group I, which would require a separate search, while the genetic processes and products of Group I are not actually required for Groups II and III, and so would not have to be searched for those groups, as stated in the last Office action.

The requirement is still deemed proper and is therefore made FINAL.

The specification is objected to for its inclusion of active hyperlinks on page 8, lines 28-29 and page 9, lines 10-11. Internet retrieval of any patent issued from the instant specification would result in the incorporation of a live web link within the text of the patent. Since the U.S. Patent and Trademark Office exercises no control over any commercial organization accessible by said hyperlink, USPTO policy does not permit the PTO to link to any commercial sites. Applicants are requested to delete the hyperlinks on pages 8-9.

The "Sequence protocol" on page 48, line 5 through page 50, line 29 should be deleted, as it is duplicative of the Sequence Listing that appears after the claims.

Claim 27 is objected to for its dependence upon non-elected claims.

Claims 3-17 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims should refer to other claims in the alternative only, and because a multiple dependent claim should not depend upon other multiple dependent claims. Thus, "one or more" as recited in claims 3-7, 9-10, 12-13, 15-17 and 27 should be replaced with

--any one or more--. In addition, claims 4-7, 9-10, 12-13, 15-17, 27 and dependents should not depend upon other multiple dependent claims. See MPEP § 608.01(n). In the interests of compact prosecution, the claims were treated on their merits. Such treatment does not relieve Applicants of responding to this objection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 provides for the use of nucleic acid molecules, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite in its recitation of "relates to" as the degree of relationship is unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to nucleic acid molecules comprising any "derivative" of SEQ ID NO:1 of unspecified sequence similarity thereto and from any source, or any "fragment" of SEQ ID NO:1 (or derivatives thereof) of any length and sequence, and plants transformed therewith. In contrast, the specification only provides guidance for the isolation of cDNA from potato comprising SEQ ID NO:1 which encodes SEQ ID NO:2, and plants transformed with the entire SEQ ID NO:1. No guidance is provided regarding the characterization of any other "derivative" from any other plant species or of any other sequence, for any "derivative" obtained by adding or subsituting or deleting an unspecified number and type of nucleotides from SEQ ID

NO:1, or for any nucleic acid molecule which is uncharacterized except for the occurrence of a "fragment" of SEQ ID NO:1 of unspecified length and sequence.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the

lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 1-17 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to monocot cells and plants transformed with nucleic acid molecules comprising the entire coding sequence of a nucleotide sequence which encodes SEQ ID NO:2, does not reasonably provide enablement for claims broadly drawn to any "derivative" or fragment of any length or sequence of SEQ ID NO:1, or the use of these

"derivatives" to effect changes in starch phosphorylation or viscosity following plant transformation therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to nucleic acid molecules comprising any "derivative" of SEQ ID NO:1 of unspecified sequence similarity thereto and from any source, or any "fragment" of SEQ ID NO:1 (or derivatives thereof) of any length and sequence, and plants transformed therewith. In contrast, the specification only provides guidance for the isolation of cDNA from potato comprising SEQ ID NO:1 which encodes SEQ ID NO:2, and plants transformed with the entire SEQ ID NO:1. No guidance is provided regarding the characterization of any other "derivative" from any other plant species or of any other sequence, for any "derivative" obtained by adding or subsituting or deleting an unspecified number and type of nucleotides from SEQ ID NO:1, or for any nucleic acid molecule which is uncharacterized except for the occurrence of a "fragment" of SEQ ID NO:1 of unspecified length and sequence. Furthermore, no guidance is provided for obtaining and evaluating the changes phosphorylation, viscosity and other properties of starch produced by plants transformed with a multitude of non-exemplified "derivatives" or "fragments".

The process of modifying starch accumulation in transgenic plants is particularly unpredictable. See Kossmann et al (1995; Progress in Biotechnology, Volume 10), who teach the lack of influence of antisense potato starch accumulation genes on branching or phosphate

content of starch (page 275, third through fifth full paragraphs), the difficulty inherent in isolating individual starch synthesis enzymes or their corresponding genes (paragraph bridging pages 275 and 276), and the lack of correlation between reduction of branching enzyme gene activity and branching of starch in transgenic plants (see, e.g., page 277, penultimate paragraph).

The process of modifying starch phosphorylation in transgenic plants is unpredictable, given the lack of correlation between the presence of the R1 putative phosphorylating enzyme and the actual degree of starch phosphorylation in a variety of plants (see, e.g., Ritte et al, page 179, Abstract and bottom paragraph of column 2; page 180, column 1, top three paragraphs; page 182, paragraph bridging the columns; page 183, column 2, top paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified "derivatives" or "fragments" of SEQ ID NO:1 from a multitude of non-exemplified sources, and to evaluate and obtain modification in starch phosphorylation and other starch properties in plants transformed with said derivatives or fragments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 15-17 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/11188 (PLANTTEC).

The claims are braodly drawn to monocot cells and plants, including wheat cells and plants, transformed with any "derivative" of SEQ ID NO:1, wherein said transformants produce starch of altered phosphorylation, viscosity, and other properties.

PLANTTEC teaches wheat plant transformation with a nucleotide sequence encoding an R1 phosphorylation enzyme in sense orientation, which nucleotide sequence has 92.9% overall similarity and 98.4% local similarity to SEQ ID NO:1, wherein plant cells and plants transformed therewith produce starch with increased phosphorylation. See the translation of PLANTTEC, Kossmann et al (U.S. Patent 6,207,880 which is a continuation of PCT/EP96/04109 corresponding to WO 97/11188), Figures 1-2; column 5, lines 33-42; column 12, lines 17-30; column 17, line 45 through column 18, line 5; column 23, lines 3-11; and claims 1, 8-9 and 12-15. See also the Sequence Search results appended to Kossmann et al. The other instantly claimed alterations in viscosity and other starch properties would have been inherent properties of the starch produced by plants transformed with "derivatives" of SEQ ID NO:1.

Claims 1-17 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/53072 (DU PONT).

The claims are broadly drawn to monocot cells and plants transformed with "derivatives" of SEQ ID NO:1 ligated to a tissue-specific promoter, wherein said transformed plants are "related to" wheat.

DU PONT teaches corn transformation with a nucleotide molecule encoding an R1 phosphorylating enzyme in sense orientation with respect to the seed-specific zein promoter, wherein the nucleotide molecule is a "derivative" of SEQ ID NO:1 because it shares 20.4% overall and 74.9% local similarity thereto (see, e.g., page 19, line 20 through page 21, line 18 and the Sequence Search result appended thereto). The instantly claimed altered starch properties would have been inherent properties of starch produced by the plants transformed with the claimed "derivatives". Corn is "related to" wheat because they are in the same plant family, namely the Graminaceae.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 19, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638